

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6484. Honegar. (F.D.C. No. 44382. S. No. 91-014 P.)

QUANTITY: Unknown quantities in 1-pt. and 1-qt. btls. at Albany, N.Y.

SHIPPED: On 2-18-60 and subsequent thereto, from Greenville, N.H., by B. T. Babbitt, Inc.

LABEL IN PART: (Btl. front panel) "Pure Honey & Apple Cidar Vinegar * * * HONEGAR * * * Honegar Division, 625 Madison Ave., New York 22, N.Y."

ACCOMPANYING LABELING: Reprint reading in part "New York Herald Tribune Honegar Found Useful as Recipe Ingredient * * * See and Hear the Honegar Story in this store today"; poster reading in part "K Kress Honegar America's Newest Home Remedy Sensation"; window streamer reading in part "You read about it in Life * * * Honegar"; display poster (inside text) reading in part "Read what Life, Time, Fortune say about Honegar"; and proof of newspaper advertisement reading in part "Would you like to try this simple 'home remedy'? * * * Honegar."

RESULTS OF INVESTIGATION: The article was shipped as described above in connection with the filling of an order for 15,000 cases of 12 1-pt. bottles each, and 10,000 cases of 6 1-qt. bottles each, which had been placed for B. T. Babbitt, Inc., with the Rowse Co., of New Hampshire, Inc., Greenville, N.H., manufacturer and packer of the article.

LIBELED: 3-21-60, N. Dist. N.Y.

CHARGE: 502(b)(1)—when shipped and while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended, namely, for the treatment of arthritis; digestive disorders; belching; vomiting and diarrhea from food poisoning; constipation; obesity; high blood pressure; chronic fatigue; headaches, including migraine headaches; all infectious diseases, including typhoid, bronchopneumonia, peritonitis, pleurisy, dysentery, fungus diseases, common cold, chicken pox, measles; all childhood diseases; heart disease; heart attacks; essential hypertension; diabetes; insomnia; sterility; difficult labor; morning sickness; nervousness; tension; irritability; itching scalp and skin; numbness; cold hands and feet; dizziness; mental retardation; tooth decay; falling hair; breaking fingernails; paranasal sinusitis; seepage from sinuses; asthma; hay fever; facial neuralgia; retarded growth; pyelitis; thickened blood; ringing in ears; impaired hearing; Menieres syndrome; callouses and corns; slow healing of cuts and bruises; pimples; tic; cramps in muscles; blocked and swollen lymph glands; coughs; infant colic; bed-wetting; hangovers; alcoholism; and to provide vigor; promote longevity; maintain good health from the cradle to the grave; to control and reduce weight without restrictions of diet; and to reduce or eliminate the difficulties of old age.

DISPOSITION: On 5-10-60, B. T. Babbitt, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the article was ordered released under bond to be brought into compliance with the law. The claimant subsequently submitted relabeling proposals to the Food and Drug Administration. Such proposals were rejected on 8-18-60, and there-

*See also No. 6483.

after, upon motion of the claimant to determine the legality of the proposed relabeling, the matter came on for hearing before the court. On 11-22-60, the court handed down the following decision :

BRENNAN, *District Judge*: "In the present phase of this proceeding, the claimant seeks the determination of this court that its proposed action in relabeling a condemned article constitutes a compliance with the provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. 301-392). The problem is pointed up by a brief background of procedure and facts set out below.

"On March 21, 1960, the United States Attorney filed a libel which prayed for the seizure and condemnation of a food article known as 'Honegar.' The United States Marshal thereafter seized 5,247 cases of bottles labeled with the trade name above and same are now the subject of this proceeding. The libel in effect charged that the seized items were in violation of the provisions of the above mentioned Act in that same, considered as a drug, were misbranded. The particular provisions of the statute involved were 21 U.S.C.A. 352(b)(1), in that the label failed to bear the name and place of business of the manufacturer, packer or distributor and 352(f)(1) in that the label thereon failed to bear adequate directions for the use for which it was intended. B. T. Babbitt, Inc., filed a claim as the owner of the seized product and filed an answer denying the essential allegations of the libel. Thereafter, upon the return day of the monition, claimant appeared and consented that a decree be entered condemning the articles seized and requested that same be returned to the claimant to be brought into compliance according to the provisions of 21 U.S.C.A. 334(d). The United States opposed the release of said article and the court exercised its discretionary power in affording such relief. An order was thereupon entered containing the usual provisions requiring that a bond be filed by the claimant and that compliance should be under the supervision of the Food and Drug Administration. It was further provided 'in the event relabeling cannot be agreed upon, and nothing in this order shall preclude the United States, from presenting proof, if any it has, that the background and past sales program make it impossible to bring it into compliance, as a food, with the Federal Food, Drug and Cosmetic Act.'

"The claimant then proceeded to negotiate with the Food and Drug Administration as to steps to be taken to place the product in compliance with the law. These negotiations culminated in a letter by claimant to the Administration dated June 29, 1960 wherein the claimant agreed to completely relabel each of the bottles, copies of the new labels being submitted with the letter. All advertising and promotional literature, seized by the Marshal, was to be destroyed and no future reference would be made to the book 'Folk Medicine' by Dr. Jarvis. The product was to be promoted and sold as a food product with no claim of therapeutic value. Same was to be marketed through claimant's sales force, food programs and food wholesalers. On August 18, 1960, claimant's proposal, as outlined above, was rejected by letter signed by the Commissioner of Food and Drugs. The bases of the rejections appear to be that the product was so connected with the contents of Dr. Jarvis' book, above mentioned, and the previous sales had been so advertised as to impress upon the public that claim was made that the product had therapeutic values to the extent that same could not be eliminated by the procedures proposed by the claimant. It was also urged that the Commissioner had determined that the product could not be successfully marketed limited as a food product. A hearing was held and evidence taken.

"Brief reference should be made to the factual background which preceded claimant's attempt to market the product in question. It seems that the medicinal qualities of honey and vinegar were advanced and discussed in a book entitled 'Folk Medicine' by Dr. Jarvis. This book was widely circulated and the offering of the product for sale by the claimant in its advertising and promotional literature leaned upon the statements contained therein. In effect, administrative determination rests upon the conclusion that the marketing of the product, through its advertising as a drug, constituted a fraud upon the public and that claimant's belated attempts to market same only as a food product are tainted with its past history.

"There is little judicial precedent to guide the court in the matter of the decision required here. Without doubt the release of the product to the claimant for the purpose of bringing same into compliance with the Act is a matter of judicial discretion. Here was a perfectly good food product, without harm in itself or to its users, condemned essentially because of the advertising and promotional material used in connection with its sale. The discretion of the court was exercised in the light of the purpose of the Act together with the principle that forfeitures are not favored.

"While the decision of the administrative body deserves respect, the decision in *Buticaps Inc. v. U.S.*, 252 F. 2d 634 indicates that the ultimate judgment of the sufficiency of relabeling is the obligation of the court.

But the terms and conditions are to be fixed by the Court and not by the Department of Health, Education & Welfare. Libelee is entitled to judicial due process. (*Buticaps v. U.S.*, supra, page 636.)

"Turning now to the merits, this court finds that the item involved is a food product. It is a mixture of honey and vinegar. Its components are plainly stated upon the proposed labels. The claimant has never been involved in previous similar law violations. Its good faith is not questioned. The libelant's contention that the article cannot be successfully sold as a food is an economic problem, the burden of which rests upon the claimant rather than upon the United States or the court. A similar product is presently marketed by at least two companies. That a segment of the public is impressed that a food product has certain therapeutic values is common to many food items in everyday use. The marketing of such items is within the law so long as baseless claims are eliminated therefrom.

"All of the above leads to the finding and conclusion that the steps proposed to be taken by the claimant in its letter of June 29, 1960, together with the amendment which strikes the words 'Fareham Farms' from the label and substitutes the words 'Sweet 'n Sour' brings the product into compliance with the law and the claimant is entitled to a judgment or order accordingly.

"The authorities cited by the United States have not been overlooked but in general they apply to the exercise of discretion in the release of a condemned product to the claimant for the purpose of bringing same into compliance with the law rather than to the question which is involved here. An order or judgment may be submitted accordingly."

In accordance with the above decision, the court entered an order on 12-22-60 directing that the article be relabeled to designate the trade name of the article as "Sweet'n Sour Honey and Vinegar," and that the original labels and all advertising and promotional material accompanying the article be destroyed.

6485. Geriatric Formula Food Supplement. (F.D.C. No. 44726. S. No. 23-236 R.)

QUANTITY: 14 cases each containing 24 186-tablet boxes, at Omaha, Nebr.

SHIPPED: 2-29-60 and 3-14-60, from Los Angeles, Calif., by Belco Products Corp.

LABEL IN PART: (Box) "XDR Geriatric Formula Food Supplement Plus * * *
A special formula from 100% Organic or Natural Sources with the exclusive XDR Base."

ACCOMPANYING LABELING: Leaflet entitled "Here is the story of XDR."

LIBELED: 7-20-60, Dist. Nebr.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for and preventive of physical and mental tiredness and depressed conditions; lack of vigor; rundown conditions; weakened blood; lack of resistance in conditions affecting capillary integrity and intercellular cement substances; colds; lack of health and proper sex function; prolonged illness